

**AMENDMENTS TO THE DRAWINGS**

The attached sheets of drawings include changes to Figures 3 and 4. These sheets, which include only Figures 3 and 4, replace the original sheets including Figures 3 and 4.

Attachment: Replacement Sheets 3/5 and 4/5.

**REMARKS**

This paper is in response to an official action dated August 22, 2006, and follows a telephonic interview between Examiner Gilbert and the undersigned attorney on December 21, 2006.

Amendments to Figures 3 and 4 and to claims 1 and 16 are submitted herewith.

It is respectfully submitted that the application is in condition for allowance, as described below.

**Terminal Disclaimer and Double Patenting Rejection**

The official action disapproved of the terminal disclaimer submitted with the amendment filed July 10, 2006, on the basis that “the assignee is not of record” (p. 2, ¶ 4 of the official action). The double patenting rejection was maintained (pp. 5-6, ¶ 14 of the official action).

It is respectfully submitted that the disapproval of the terminal disclaimer was without basis in the rules. See 37 CFR § 1.321 (the disclaimer need only “state the present extent of applicant’s or assignee’s ownership interest in the patent to be granted”) and MPEP § 1490: “Where the attorney or agent of record signs the disclaimer, **there is no need** to comply with 37 CFR § 3.73(b)” (emphasis in original).

Nevertheless, the assignment has now been recorded against the present application, and a revised terminal disclaimer is submitted herewith. Entry of the terminal disclaimer and withdrawal of the double patenting rejection are hereby solicited.

The fee for the terminal disclaimer has already been paid with the previous submission, and has not been refunded. Accordingly, it is believed that no fee is due; however, the Commissioner is hereby authorized to charge Deposit Account 13-2855 under order number 29473/11372A if a fee is found to be due in connection with the terminal disclaimer.

**Drawings**

The drawings were objected to for failing to comply with 37 CFR § 1.84(p)(4) because the lead lines for reference characters 10 and 15 were not clear. The lead lines have been corrected, support being found in the original application, for example at p. 7, first paragraph, p. 9, penultimate paragraph, and Examples 5 and 6 on pp. 16-17. In each figure,

reference numeral 10 now clearly corresponds to permeable membrane and reference numeral 15 corresponds to the contact adhesive.

Corrected drawings on replacement sheets are submitted herewith.

### **Claim Objections**

Claim 1 was objected to for informalities on the alleged basis that it recited “-,” on line 3. The designation objected to on line 3 is apparently the comma which was deleted by way of strikeout type font (i.e., “,”). The amendments to the claims submitted herewith incorporate the previous amendments. Agreement was reached that the objection would be withdrawn.

### **Claim Rejections – 35 USC § 102**

The claims, before and after the amendments submitted herewith, are distinguished from the cited references in that the prior art references are related to iontophoretic systems, wherein the current flows through the body of the patient, whereas in the claimed invention it does not. This fundamental difference in operation is the result of fundamental differences in structure between the prior art and the claimed structure.

As agreed in the December 21, 2006, telephonic interview, and with a view to advancing the application to allowance, the claims are presented for amendment to recite that the reservoir is “stacked” between the carrier layer (comprising one or more electrodes) and one or more counter electrodes. See the amendments to independent claims 1 and 16.

No difference in claim scope is intended.

In view of the remarks below, further reconsideration is respectfully requested. If upon review of the remarks below the examiner agrees that the unamended claims fully distinguish the prior art, then the examiner is requested to not enter the amendments to the claims, and to pass the application to allowance.

To complete the record, the most stark differences between the claimed structure and the cited prior art are addressed for each reference.

Henley U.S. Patent No. 5,415,629

Claims 1, 2, 6, 7, 11, 12, and 14 were rejected under § 102(b) as anticipated by Henley (p. 3, ¶¶ 9-10).

The Henley reference is clearly lacking both a reservoir containing said substance to be delivered, the reservoir formed by a contact adhesive and provided between the carrier layer and one or more counter electrodes.

The reservoir of Henley is not “formed by” a contact adhesive. Instead, in the apparatus of Henley the medicament-carrying layer 18 is “attached to” the conductive matrix “by” an adhesive. See col. 7, lines 61-63.

Rather than being formed from a contact adhesive, the medicament-carrying layer is “preferably formed from a porous material about ¼ of an inch thick which can be a honey-combed sponge-like open-celled material with cells preferably vertical to the skin to minimize cross flow or lateral dispersion of the medicament.” See col. 7, lines 63-68.

The reservoir of Henley is also not “provided between the carrier layer and one or more counter electrodes.” In the apparatus of Fig. 1, and the corresponding description in the cited portions of columns 7 and 8, there is no counter electrode (“grounding electrode” in the nomenclature of Henley) shown and no location is provided for it. See, e.g., col. 7, line 68, to column 8, line 3. In addition, however, the description makes it clear that the counter electrode of Henley is located remote from the electrode 14 / medicament-carrying layer 18 pair in Fig. 1 because it states: “The grounding electrode . . . must cover an area [of skin] similar in size to the area [of skin] covered by the multichannel electrode.” This is entirely consistent with the operation of an iontophoretic device, as explained in Henley (e.g., col. 7, lines 47-48) and in the background section of the pending application (e.g., p. 3, second full paragraph). The “watch band” embodiment shown in Fig. 2 of Henley confirms this interpretation of the description, wherein it is shown that the neutral electrode array is located remote from the active electrode array, on a different portion of skin around the user’s wrist. (See also col. 4, lines 21-27.) Thus, the reservoir is not disposed “between the carrier and one or more counter electrodes” as presently claimed.

Furthermore, the Henley reference omits disclosure of a carrier layer “impermeable to a substance to be delivered”, of a “removable film”, and of an integrated controller microchip that is “fixed to the carrier layer.”

Gyory et al. U.S. Patent No. 6,083,190

Claims 1 and 12-14 were rejected under § 102(e) as anticipated by Gyory et al. (p. 4, ¶¶ 11-12).

The Gyory et al. reference is clearly lacking both a reservoir containing said substance to be delivered, the reservoir formed by a contact adhesive and provided between the carrier layer and one or more counter electrodes.

The reservoir of Gyory et al. is not “formed by” a contact adhesive. Instead, in the apparatus of Gyory et al. the alleged reservoirs (“16, 18”) are,

formed of any material adapted to absorb and hold a sufficient quantity of liquid therein in order to permit the passage of the agent therethrough by electrotransport. Since water is the preferred liquid solvent for forming the solutions contained in reservoirs 16 and 18, the reservoirs preferably contain one or more hydrophilic polymers such as polyvinylpyrrolidone, polyvinyl alcohol, or polyethylene glycols, optionally mixed with a hydrophobic polymer such as polyisobutylene, polyethylene, and/or polypropylene.

See col. 6, line 64, to col. 7, line 6. Thus, contact adhesives are not disclosed or suggested with respect to the reservoir. Instead, the contact adhesive of Gyory et al. is a separate element 28 which is remote from the reservoirs and disposed about the periphery of the device, or between the reservoirs 16, 18 and the body surface. See Fig. 1 and col. 36-42.

The reservoir of Gyory et al. is also not “provided between the carrier layer and one or more counter electrodes.” The alleged carrier layer is elements 12 and 14, and the alleged reservoir is elements 16 and 18. The official action does not identify the alleged counter electrode, so it is unclear what the basis is for the rejection. However, the reference identifies element 12 as the donor electrode and element 14 as the counter electrode (col. 6, lines 57-58). Thus, assuming *arguendo* that in the intended interpretation element 12 is the carrier layer and element 14 is the counter electrode, then with reference to Fig. 1 the element “between” the carrier layer and counter electrode is element 20. However, element 20 is an electrical insulator, not a reservoir. See col. 7, lines 6-13.

Furthermore, the Gyory et al. reference omits disclosure of a “removable film”, and of a reading and writing device for writing onto an integrated controller microchip.

Keusch et al. U.S. Patent Application Publication No. 2002/0062102

Claim 1 was rejected under § 102(e) as anticipated by Keusch et al. (pp. 4-5, ¶ 13).

The Keusch et al. reference is clearly lacking both a reservoir . . . provided between the carrier layer and one or more counter electrodes and an integrated controller microchip that is fixed to the carrier layer.

The reservoir of Keusch et al. is not “provided between the carrier layer and one or more counter electrodes.” Instead, the alleged electrodes (e.g. electrode 112) is between the “carrier layer 111” [sic, 111 is a surface of 110] and the reservoir (e.g., reservoir 120). See Fig. 3, showing a cross-section view of the anode reservoir-electrode of Fig 2.

In addition, the alleged integrated controller microchip is not “fixed to the carrier layer.” In Keusch et al., “schematic” Fig. 1 and related description at [0022], the controller 2 is clearly not fixed to the carrier layer / backing 18. Instead of being physically connected, it is “connected electrically” by conductive leads 8a and 8c. *Id.* See also Fig. 2 and the accompanying description at [0023] – [0024]. There is no description of an integrated controller microchip. The only description which hints at such structure is the final sentence of [0025]: “Power supply 130 and backing 110 includes a circuit 139 to identify the particular type of reservoir-electrodes and medicament to power supply 130.” “Circuit 139” is simply a trace between connectors 134. If this description is to be given any substantive interpretation, it appears that a controller, if one is to be inferred, is located with the power supply 130, rather than fixed to the backing 110. The circuit is thereby formed through the connectors 134 when power supply 130 is connected. There is no other structure shown or described with respect to backing 110.

Furthermore, the Keusch et al. reference omits disclosure of a “removable film”, and of a reading and writing device for writing onto an integrated controller microchip.

CONCLUSION

In view of the foregoing, withdrawal of the rejections and allowance of all pending claims are respectfully requested. Should the examiner wish to discuss the foregoing, or any matter of form or procedure in an effort to advance this application to allowance, the examiner is urged to telephone the undersigned attorney at the indicated number.

Respectfully submitted,

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